IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ERFINDERGEMEINSCHAFT UROPEP GbR, Plaintiff, v. ELI LILLY AND COMPANY, and BROOKSHIRE BROTHERS, INC., Defendants.	)	CASE No. 2:15-cv-01202-WCB

PLAINTIFF UROPEP'S OPPOSITION TO DEFENDANT'S MOTIONS IN LIMINE

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INTRODUCTION

Lilly asks the Court to exclude relevant, admissible evidence of Lilly's litigation conduct. Lilly also seeks to prevent the effective cross examination of one of its experts, who has obtained a patent indistinguishable from UroPep's for § 112 purposes and with a laundry list of medical uses for PDE5 inhibitors but no mention of BPH – exposing Lilly's § 103 case for the hindsight driven endeavor it is. Lilly also wants to prevent UroPep from arguing that its patent enjoys a presumption of validity. One common thread through Lilly's motion is a purported concern with evidence that may confuse the jury. *See* Dkt. 198, Lilly MIL at 1, 6-8. But the complexity or potential for confusion from the evidence and argument that Lilly seeks to preclude pales in comparison to the complex technical and economic issues this trial will inevitably address.

Moreover, any risk of confusion is overcome by the importance of the evidence. Lilly's litigation conduct is relevant to a key question of willfulness: whether Lilly has, in fact, held a reasonable belief of non-infringement. Lilly cannot – as it has done here – invoke its litigation positions as evidence of a reasonable belief of non-infringement, and then prevent UroPep from showing that those positions are not in fact reasonable or genuine. Similarly, other patents in the field of PDE inhibition – including Lilly's and its experts' patents – will help provide the appropriate context for the jury to understand the disclosures that a person of skill in the art would expect to be included in this type of patent. Lilly and its experts should not be allowed to take positions on this issue that are inconsistent with their own patents, or others' patents in the field, and then prevent UroPep from showing the jury that the disclosures in the '124 patent match-up well to the disclosures included in similar patents in the same field. Finally, UroPep's patent does, in fact, enjoy a presumption of validity. To the extent that UroPep determines it will aid its presentation to the jury to refer to that presumption, it should have the freedom to do so.

ARGUMENT

I. UroPep's Willfulness Evidence Is Admissible

Lilly seeks a discovery sanction precluding UroPep from relying on Lilly's litigation tactics as evidence of willfulness due to UroPep's failure to list this information in its interrogatory response. *See* Dkt. 198, Lilly MIL at 3-5. But the vast majority of the litigation tactics that UroPep contends are relevant to willfulness occurred over the last several weeks, and UroPep promptly informed Lilly that its tactics are relevant to willfulness. Federal Rule of Civil Procedure 26 does not require supplementing an interrogatory response where, as here, the other party was made aware of the relevant information within weeks of its occurrence.

Moreover, until Lilly filed its motion for summary judgment of no willfulness, Lilly had never informed UroPep that it intended to rely on its allegedly reasonable belief in non-infringement to rebut UroPep's willfulness claim. Lilly has now made it clear that, even though it has not disclosed any evidence of an alleged belief of non-infringement, it intends to rely on the positions it has taken in litigation to rebut UroPep's willfulness claim. Lilly cannot invoke the reasonableness of its litigation positions as evidence of non-willfulness and then preclude UroPep from introducing evidence showing that Lilly's litigation positions have not, in fact, been reasonable.

A. The Evidence of Litigation Conduct That Lilly Seeks To Exclude Mostly Occurred Over The Last Several Weeks

Federal Rule of Civil Procedure 26(e)(1) provides that "[a] party who has . . . responded to an interrogatory . . . must supplement or correct its disclosure or response: (A) in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, *and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing.*" (emphasis added).

The vast majority of the litigation conduct that is relevant to willfulness has occurred over the last several weeks, and UroPep promptly informed Lilly of their relevance to willfulness:

- On January 17, 2017, Lilly filed its motion for summary judgment of noninfringement. *See* Dkt. 174. In that motion, Lilly argued that UroPep could not show infringement based on Lilly's selectivity data for tadalafil, because Lilly's data came from tests that used recombinant-derived PDEs, as opposed to fractionated PDEs from live tissue. *Id.* at 12-14. Lilly argued that this was "fatal" to UroPep's infringement case. *Id.* at 13. But, in its motion for summary judgment of anticipation filed that same day, Lilly relied on a declaration from its employee expert, Dr. Florio, that addressed the selectivity of icariin. *See* Dkt. 172, Lilly SJ Mtn. Anticipat. at 6-8, 11-12. In that declaration, Dr. Florio also stated that "in my experience, use of recombinant human PDE5 rather than PDE5 derived from human corpus cavernosum should not materially affect the IC50 results." Dkt. 189-18, Florio Decl., ¶ 10. Neither of Lilly's briefs acknowledged the inconsistency between Lilly's non-infringement argument and the declaration it sought to rely on to prove anticipation. UroPep raised this issue two weeks later, in its response to Lilly's summary judgment motions. *See* Dkt. 189, UroPep Resp. SJ. Infring. and Indefin. at 23-24.

- Lilly also argued, in its non-infringement motion, that it didn't matter that PDE11 had not been discovered by July 1997, because a peak fraction test of a PDE inhibitor on prostatic tissue would "likely" show PDE11 "in a peak fraction" and demonstrate that a peak fraction test of tadalafil "would likely not support the required 20-fold selective threshold." Dkt. 174, Lilly SJ Mtn. Noninfring. at 13. Two weeks later, UroPep pointed out two problems with Lilly's position. First, the only evidence Lilly cited to support these statements – Dr. Beavo's expert report – did not say that such a result was likely. Instead, Dr. Beavo said that it "might … if … could potentially" happen. See Dtk. 189, UroPep Resp. at 2, 26. Second, Lilly has sponsored a paper, written by its own employee experts, finding that only one isozyme of PDE11 is present in the prostate – PDE11A4 – and that tadalafil is 40 times more potent against PDE5 than PDE11A4. Id. at 30.

- In its reply in support of its non-infringement motion, Lilly argued that the '124 patent claims' selectivity requirement can be read to apply to PDEs 6-11 because "it may not necessarily be true" that this would read out all the preferred embodiments. Dkt. 200, Lilly Reply at 11. Lilly explained that "some assays could be used to show that zaprinast is, sometimes, within the scope of the claims." *Id*. at 11 n.7. Lilly's argument contradicts its own indefiniteness motion, as well as its own expert's report. Dr. Rotella assembled a chart summarizing selectivity data on zaprinast from various sources. See Dkt. 189-2, Rotella Resp. Rpt., ¶ 25. Dr. Rotella's chart indicates that zaprinast is actually more potent against PDE6 than PDE5. Id. UroPep pointed out this inconsistency just one week later, in its Sur-reply brief. See Dkt. 217, UroPep Sur-reply at 13-14.

Lilly cannot obtain a litigation sanction for late disclosure when UroPep informed Lilly of its position within a week or two of the events that form the bases for UroPep's positions.

B. Lilly Cannot Avoid Willfulness By Alleging That It Has A Reasonable Belief Of Non-Infringement, And Simultaneously Preclude Evidence That Lilly's Purported Belief Is Neither Genuine Nor Reasonable

The only evidence of willfulness that UroPep seeks to rely on that UroPep did not add to its interrogatory response, and that did not occur over the last month, is evidence regarding the positions Lilly advocated during the first round of summary judgment motions. But UroPep seeks to introduce this evidence to rebut Lilly's contention that its litigation positions indicate that Lilly had a reasonable belief in non-infringement – a contention that Lilly raised for the first time in its motion for summary judgment of non-willfulness. In that motion, Lilly argued for the first time that "after notice of the '124 patent was given Lilly had, and still has, a good faith belief that there is no infringement." *See* Dkt. 174, Lilly SJ Mtn. Noninfring. at 16. Lilly continued to explain that its proposed construction of the PDE5 inhibitor claim term (*i.e.*, that is a "means plus function" claim term) was reasonable and showed that Lilly had a genuine basis for believing it did not infringe. *Id.*

Prior to filing its motion for summary judgment of non-willfulness, Lilly never presented an opinion of counsel defense, or otherwise indicated an intent to rely upon its litigation positions to rebut UroPep's willfulness allegations. UroPep does not agree that Lilly's litigation positions are sufficient to show its actual beliefs regarding infringement. As Lilly itself points out, "a vigorous defense is entirely proper." Dkt. 200, Lilly Reply at 20. Lilly's "vigorous defense" may well include positions that Lilly, as a company, does not subjectively believe should prevail, and it is Lilly's subjective belief, not the objective reasonableness of its positions, that determines whether Lilly's infringement is willful. *See Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S.Ct. 1923, 1932-34 (2016) (eliminating the rule that allowed defendants to avoid willfulness simply by presenting an objectively reasonable defense). But, to the extent Lilly seeks to rely on its litigation positions to rebut UroPep's willfulness claims, UroPep should be

allowed to rebut Lilly's defense with evidence showing that Lilly's positions are not, in fact, reasonable and could not be the genuinely-held positions of a sophisticated drug company.

Evidence that Lilly's claim construction positions were neither genuine nor reasonable includes, for example, the fact that Lilly's proposed "means plus function" construction of the PDE5 inhibitor claim term was in direct opposition to Federal Circuit precedent holding that "means plus function" analysis does not apply to method claims. As this Court noted, the Federal Circuit's decisions in *Epcon Gas Sys. Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022 (Fed. Cir. 2002) and *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576 (Fed. Cir. 1997), demonstrate that "means plus function analysis is not applicable to the method claims at issue in this case." Dkt. 149, Mem. Op. & Order at 9. Lilly should not be allowed to tell the jury that its infringement is not willful because it had a good faith belief that the claims only covered the disclosed embodiments, but then preclude UroPep from showing that a sophisticated company like Lilly could not have believed that "an inhibitor of phosphodiesterase (PDE) V" is a means plus function claim term.

Similarly, in its motion for summary judgment for lack of written description, Lilly argued that the '124 patent's disclosure was inadequate because "the field of PDE inhibitors was emerging and unpredictable." Dkt. 120, Lilly WD Br. at 3. The Court noted in its decision denying Lilly's motion that UroPep identified "evidence in the record that persons of skill in the art would have been aware of hundreds of PDE V inhibitors." Dkt. 149, Mem. Op. & Order at 36. Lilly should not be allowed to argue that it reasonably believed the '124 patent's disclosure was inadequate because the relevant field was nascent, but then exclude evidence showing that its position is inconsistent with the state of the art at the time.

Lilly also tries this heads-I-win, tails-you-lose approach with its arguments regarding the validity of the '124 patent. As discussed below (*infra* § II.B), Lilly asserts that the patent does

not meet the written description and enablement requirements because a person of skill in the art would expect to see certain features in the specification (e.g., *in vivo* data). But these same features supposedly "missing" from the '124 patent are also "missing" from Lilly's patents. Lilly has obtained valuable patent rights in the PDE inhibition field, including those patents listed in the Orange Book for Cialis. Lilly uses these patents to exclude competitors like Pfizer from the marketplace. Lilly's efforts to avoid liability on a patent by challenging the level of disclosure in the specification – while capitalizing on patents with an identical level of disclosure – further highlights its willful conduct.[1]

C. Lilly's Litigation Tactics Are Relevant To Willfulness And Will Not Confuse The Jury

Lilly also argues that UroPep's evidence of willfulness should be excluded because it "will not be understandable to a lay juror." Dkt. 198, Lilly MIL at 5. But the complexity of the evidence of Lilly's willfulness pales in comparison to the complexity of the technical and economic issues in this case. Moreover, juries have long considered the reasonableness of parties' beliefs of non-infringement when making willfulness determinations. *See, e.g.*, Fed. Cir. Bar Assoc. Model Patent Jury Instruction 3.10, Willful Infringement (listing "[w]hether or not [alleged infringer] reasonably believed it did not infringe" as one of the factors to be presented to the jury in a willfulness instruction). *See also WesternGeco L.L.C. v. ION Geophysical Corp.*, 837 F.3d 1358, 1364 n.2 (Fed. Cir. 2016) (citing, without disapproval, a jury instruction on subjective willfulness that included whether or not "there is a reasonable basis to believe that the infringer . . . had a reasonable defense to infringement").

[1] Lilly will no doubt complain that UroPep did not list Lilly's or its expert's patents in its interrogatory response on willfulness. But Lilly does not need UroPep to inform Lilly of patents that it or its experts own, let alone patents that Lilly has included in Orange Book entries for its drugs. Lilly is fully aware of these patents.

Lilly's litigation conduct is relevant to willfulness. *See Robertson Transformer Co. v. Gen. Elec. Co.*, No. 12 C 8094, 2016 WL 4417019, at *8 (N.D. IL 2016) (rejecting argument that "post litigation conduct is 'irrelevant' to willfulness"); *Boston Scientific Corp. v. Cordis Corp.*, 838 F. Supp. 2d 259, 279 (D. Del. 2012), *aff'd*, 497 Fed. App'x 69 (Fed. Cir. 2013) (enhancing damages where defendant's "knowledge of the patent and lack of any defenses," and defendants' "litigation conduct, weigh[ed] heavily in favor of enhancement"). Lilly should not be allowed to exclude relevant evidence of willfulness on the dubious claim that it would confuse the jury.

II. Evidence Or Argument Regarding Other Patents, Including Patents Held By Lilly, Its Experts, And Others, Is Admissible

Lilly seeks to exclude relevant facts that contradict its arguments. For example, Lilly's expert Dr. Rotella proffers an opinion that using a selective PDE5 inhibitor to treat BPH would have been obvious in July 1997. But that is not what Dr. Rotella thought in July 1997. The evidence? Dr. Rotella's U.S. Patent No. 6,087,368. Dr. Rotella and his drug development team at Bristol-Myers Squibb filed for the '368 patent less than a year after the '124 patent's priority date. The patent covers millions of selective PDE5 inhibitors and includes method of treatment claims for more than twenty ailments. But Dr. Rotella's drug development team did not include BPH in that patent. Ex. 1, '368 patent; Ex. 2, Rotella Dep Tr. 155:25-156:4. Similarly, other patents covering various PDE5 inhibitors and methods of treatment using PDE5 inhibitors (including some owned by Lilly) provide relevant context to help the jury understand the types of disclosures that others, including Lilly, have found to be sufficient for purposes of § 112. Lilly's other patents are party admissions as to what is an adequate disclosure and meets the enablement standard. They are relevant and admissible.

Lilly has raised several factual issues in this case, including obviousness, written description, and enablement. Lilly cannot both seek to avoid liability by presenting fact-based

arguments to the jury and simultaneously preclude UroPep from presenting Lilly's own admissions made in the same technical context that are contrary to Lilly's arguments.

A. Evidence And Argument About Dr. Rotella's Patent Is Admissible

Lilly's expert Dr. Rotella opines that the '124 patent is invalid as obvious, and for not meeting the written description and enablement requirements. Naturally, Lilly wishes to stop UroPep from cross-examining Dr. Rotella about his own patent covering millions of PDE5 inhibitors and dozens of medical treatments using them because it is exactly as infirm as Dr. Rotella says the '124 patent is. Ex. 2, Rotella Dep. Tr. 148:1-178:8. Dr. Rotella's patent provides evidence that (1) the invention disclosed in the '124 patent was not obvious, and (2) the '124 patent provides the right kind of information to a person of skill in the art to meet the written description and enablement requirements. Even independent of the fact that this is admissible evidence in its own right, the '368 patent is fair game for cross-examination, as the jury should have the chance to assess whether Dr. Rotella is credible when he attacks the '124 patent on bases he admits are also present in his own patent.

Dr. Rotella opines that the '124 patent is obvious because using a selective PDE5 inhibitor to treat BPH was obvious in 1997. Ex. 2, Rotella Dep. Tr. 108:9-16. The '368 patent was filed in June 1998, less than a year after the priority date of the '124 patent. Dr. Rotella admits that he and his fellow inventors – a drug development team at Bristol-Myers Squibb – were people skilled in the art. *Id*. 148:5-149:7. Dr. Rotella admits that the '368 patent is about PDE5 inhibitors. *Id*. 153:8-9. Dr. Rotella admits that the patent covers a large number of potential treatments, including hypertension, heart failure, myocardial infarction, strike, asthma, sexual dysfunction in men, and sexual dysfunction in women (over twenty treatments in total). *Id*. 154:21-155:24. But despite covering approximately two dozen treatments, Dr. Rotella's drug development team did not think to include benign prostatic hyperplasia. *Id*. 155:25-156:4. The

'368 patent provides significant evidence that the treatment of BPH was not obvious to a person of skill in the art in the late 1990s:

> Q: It was not obvious to your team at Bristol-Myers Squib in 1998 that a potential use of these PDE5 inhibitors that you had discovered was the treatment of BPH, correct?
>
> Mr. Barron: Objection, form.
>
> A: This program was aimed very squarely and very directly at inhibition of PDE5 for treatment of erectile dysfunction. And as a result, that's a decision that was made, not by me, but by others. And I don't know if it was obvious to them or not. I know that when we were carrying out this program, our focus was on exploring the use of these molecules for treatment of erectile dysfunction. Furthermore, that wouldn't exclude us – had there been some success, that wouldn't have prevented us from exploring their use in other methods.
>
> Q: Dr. Rotella, is allergic asthma erectile dysfunction?
>
> A: With the proviso that I'm not a physician, no.
>
> Q: There's a whole list of conditions that are not erectile dysfunction in columns 16 and 17 of your patent on PDE5 inhibitors, correct?
>
> A: That's correct.
>
> Q: And none of those conditions that are not erectile dysfunction that your team at Bristol-Myers Squibb put in your patent of PDE5 inhibitors, is the treatment of BPH, correct?
>
> A: That's correct. It's not clear to me what the relevance is to the '124 patent.

Ex. 2, Rotella Dep. Tr. 156:5-157:10.

Second, Dr. Rotella opines that the '124 patent fails to meet the written description and enablement requirements because there is no quantitative *in vitro* data (just qualitative *in vitro* data), and no *in vivo* data, in the patent. Ex. 3, Rotella Rpt. ¶¶ 209-213. He also adopts Dr. Roehrborn's opinion that the examples provided in the '124 patent are non-functional

because, for example, the dose ranges are very broad. *Id*. at ¶ 227 (citing Ex. 6, Roehrborn Rpt., ¶ 34). But the '368 patent, like the '124 patent, contains only qualitative *in vitro* data. Ex. 2, Rotella Dep. Tr. 164:1-6. The '368 patent, like the '124 patent, does not disclose numerical *in vitro* data about activity. *Id*. 164:22-25. The '368 patent, like the '124 patent, has no *in vivo* data of any kind. *Id*. 165:7-166:22. Indeed, the '368 patent has no data at all about testing in humans or animals. *Id*. 168:2-16. And the '368 patent, like the '124 patent, provides a very large dose range. *Id*. 169:9-170:16. Contrary to Dr. Rotella's opinion, the '368 patent presents significant evidence that the '124 patent provides exactly the sort of disclosure a drug development team in the late 1990s would expect to be in a patent:

> Q: And on this patent that you're an inventor on from Bristol-Myers Squibb, there is zero quantitative *in vitro* data, correct?
>
> A: There is none.
>
> Q: And on this patent that you're an inventor on from Bristol-Myers Squibb, there is zero *in vivo* data whatsoever, correct?
>
> A: That is correct. And as I have stated again, repeatedly, we obtained that data and were in possession of the data. It was the company's decision at the time not to include that data as a part of patent applications. I don't know whether that data was discussed or presented to the patent office. I don't know any of those details, and so I can't comment any further outside of reciting to and reading the claims.
>
> Q: And Dr. Rotella, Claim 11 of the patent is a method for treatment of one of the following disorders: hypertension, angina, heart failure, restenosis, atherosclerosis, dyslipidemia, reduced blood vessel patency, thrombus, either venous and arterial, myocardial infarction, peripheral vascular disease, stroke, bronchitis, chronic asthma, allergic asthma, allergic rhinitis, glaucoma, diseases characterized by disorders of gut motility, and forms of cancer responsive to the inhibition of cGMP PDE, comprising the step of administering to a mammal in need thereof an amount effective, therefore, of one or more compounds of Claim 1." Do you see that?

A: Yes, I do.

Q: Bristol-Myers Squibb has a patent bearing your name on a method of treating any of these diseases using any of the millions of compounds of Claim 1 without any quantitative *in vitro* data and without any *in vivo* data, correct?

Mr. Barron: Objection; form.

A: As I said, that data is not presented in the patent. It is conceivable – there is information in the prior art that illustrates the potential use of cGMP PDE inhibitors, in this case PDE5, for treatment of these disorders, many of which involved smooth muscle.
And so by relaxation of smooth muscle -- in fact, Pfizer investigated originally sildenafil for treatment of angina. And so that was consistent with what was known at the time when Pfizer began its investigations of PDE5 inhibitors.

Ex. 2, Rotella Dep. Tr. 176:11-178:8.

The ’368 patent should be admissible regardless of the named inventors. But the import of the ’368 patent is heightened here because it is Dr. Rotella’s patent, and thus goes to the credibility of his expert opinions. Dr. Rotella cannot represent one thing out of court – at the relevant time, in a PDE5 inhibition patent, with method of treatment claims – and then take a different opinion in Court years later without being cross-examined about those prior out of court statements. That is not how the adversary process works. The ’368 patent is admissible because it shows what a person of skill in the art – people like Dr. Rotella and his drug development team – would have expected to see in valid patents about PDE inhibition in the late 1990s.

B. Lilly’s PDE Inhibitor And Cymbalta Patents Are Admissible

Written description and enablement are not evaluated in a vacuum. For example, factors considered in evaluating enablement include (1) the quantity of experimentation necessary, (2) the amount or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*,

858 F.2d 731, 737 (Fed. Cir. 1988). Lilly argues that "compliance with the written description and enablement requirements is to be determined based on the disclosure of the '124 patent." Dkt. 198. Lilly MIL, at 6 (citing *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). The implication is that the disclosure *alone* is the factual predicate for determining compliance with these requirements. That is just not true; other evidence must be considered.

The one case Lilly cites, *Genentech*, does not support its position. *Genentech* holds that a patentee cannot meet the enablement requirement by saying all disclosures related to the inventive process are within the skill of the art. *Genentech, Inc.*, 108 F.3d at 1366. That is not the issue here. Rather, the question is what type of information a person of skill in the art would expect to be included in a method of treatment patent; for example, whether *in vivo* data is required. Written description and enablement fundamentally involves a factual inquiry. *See Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006) ("Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date. Enablement is a question of law involving underlying factual inquiries.") (citations omitted); *In re Wands*, 858 F.2d at 737 (holding that enablement is a "conclusion reached by weighing many factual considerations"). References to other patents can provide helpful, relevant evidence on these key issues.

Examples abound. As stated above, Lilly's expert Dr. Rotella proffers the opinion that the '124 patent lacks a written description because it does not have *in vivo* data. Ex. 3, Rotella Rpt. ¶¶ 209-213. UroPep's expert Dr. Bell disagrees with this opinion, noting that a person of skill in the art would still be able to understand the patent. Ex. 4, Bell Validity Rpt. ¶¶ 93-97. Dr. Bell's opinion is supported in part by Lilly's U.S. Patent No. 6,369,059. Ex. 5, '059 Patent. The '059 patent, which has a 1994 priority date, has claims covering the treatment of humans (and

nonhumans) through PDE inhibition. Ex. 4, Bell Validity Rpt. at ¶ 95. The data supporting the patent are *in vitro* tests; there are no *in vivo* tests. *Id*. at ¶¶ 96-97. That is because a person of skill in the art did not need to see *in vivo* tests in PDE inhibition patents for those patents to meet the written description requirement. Lilly's '059 patent is a party admission that UroPep is right and Lilly is wrong.

Next, Lilly's expert Dr. Roehrborn proffers an opinion that the '124 patent is not enabled because a number of items are missing. Ex. 6, Roehrborn Rpt. ¶ 149. The supposed "missing" items include (1) minimum or desired potency, (2) dosing ranges, (3) *in vivo* actions and clinical effects, and (4) desired PK characteristics. Ex. 4, Bell Validity Rpt. ¶ 161. Dr. Bell again disagrees that these are items a person of skill in the art would expect to see: Neither Lilly's Cymbalta patent nor Dr. Bell's sildenafil patent include minimum or desired potency. *Id*. Neither Lilly's Cymbalta patent nor Dr. Bell's sildenafil patent have meaningful dosing ranges, as the included dosing ranges are so large they encompass effectively the largest pill anyone could physically take. *Id*. Neither Lilly's Cymbalta patent nor Dr. Bell's sildenafil patent have *in vivo* action data or clinical data. *Id*. And neither Lilly's Cymbalta patent nor Dr. Bell's sildenafil patent have desired PK characteristics. *Id*. These patents are party admissions that the supposed "missing" items are not things a person of skill in the art would expect to see.

Finally, Lilly says the '124 patent is indefinite because "IC50 values and selectivity ratios can vary widely depending upon the experimental conditions used." Dkt. 173, Lilly Indef. Br. 13. Once again, that is not what Lilly's drug development team and a person of skill in the art expected in the late 1990s. The proof? Patents filed in the late 1990s by people of skill in the art, such as Lilly's U.S. Patent No. 6,451,807, also relied on IC_{50} ratios and made similar disclosures about source material and assay conditions. Dkt. 189, UroPep Resp. Indefinit. & Noninfring. at

1, 13-17; Ex. 7, '807 Patent. Lilly's own patent, and the 146 other patents that include IC_{50} ratio in their claims, are relevant and admissible evidence that a person of ordinary skill would have been comfortable, at the time of the invention, relying on IC_{50} ratios to define the bounds of an invention.[2]

The patents Lilly wants to exclude from this case are not, as Lilly suggests, unrelated patents UroPep will use only for prejudicial purposes. These patents provide context for how a person of skill in the art would read a patent directed to that person of skill. Lilly's concern that the jury will be "confused" by too much patent talk rings hollow. Lilly should not be allowed to exclude such relevant evidence.

III. Reference To The '124 Patent's Presumption Of Validity Is Permissible

Lastly, Lilly moves *in limine* to exclude any reference to the presumption of patent validity. The basis of Lilly's motion is that jurors might be confused by evidence or argument that "bolstered" their burden of proof. Dkt. 198, Lilly MIL, at 9. But rather than explain how this evidence would create any confusion about the burden of proof, Lilly instead makes a general reference to Rule 403 and the "reasons stated in prior cases." *Id*.

Contrary to Lilly's bare assertion, courts routinely deny similar motions because reference to the presumption of validity *helps explain* the relevant standard of proof. *See Fleming v. Escort, Inc.*, No. 1:CV 09-105-BLW, 2012 WL 1995069, at *4 (D. Idaho Jun. 4, 2012) (denying motion to preclude plaintiff from referencing presumption of validity because the reference can explain why the clear and convincing standard is used); *Volterra Semiconductor Corp. v. Primarion, Inc.*, No. C-08-05129 JCS, 2011 WL 4079223, at *1 (N.D. Cal. Sept. 12, 2011) (same); *see also Ultratec, Inc. v. Sorenson Comm., Inc.*, No. 13-cv-346-bbc, 2014 WL

[2] As UroPep has noted elsewhere, indefiniteness is an issue of law for the Court. *See, e.g., Droplets, Inc. v. Overstock, Inc.*, No. 2:11-CV-401-JRG-RSP, 2015 WL 11120799, at *2 (E.D. Tex. Jan. 9, 2015).

4955302, at *1 (W.D. Wis. Oct. 1, 2014) (denying similar motion and "instructing jur[y] about the presumption and permitting the lawyers to refer to it in their arguments").

In *Fleming*, the defendant relied on *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004) – the same case cited by Lilly here – and moved to preclude the plaintiff from discussing the presumption of validity on the grounds it would confuse the jury. *Fleming*, 2012 WL 1995069, at *4. The Court noted that the holding in *Chiron* was that it is not error to omit a jury instruction on the presumption of validity. But it did not preclude such an instruction. *Id*. ("[N]o case holds that it is error to allow counsel to argue – or the Court to instruct – that the patents are presumed valid."). The simplest way to avoid juror confusion is to explain the relationship between the presumption of validity and the requirement that a defendant prove invalidity by clear and convincing evidence. *Id*. (citing *Volterra*, 2011 WL 4079223).

The cases cited by Lilly do not show otherwise. In fact, some say the exact opposite. *Alloc, Inc. v. Pergo, Inc.*, No. 02-C-0736, 2007 WL 5289735, at *1 (E.D. Wis. Nov. 21, 2007) ("There is little danger of jury confusion over the phrase 'presumption of validity' if the jury is simply instructed that the phrase means that the Alloc Parties have the burden of proving by clear and convincing evidence that each claim is invalid."). Others are unrelated to what a jury should even hear. *Avia Grp. Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1562 (Fed. Cir. 1988) (holding that the presumption of validity is not waived by patentee who waits until rebuttal on summary judgment to present evidence on validity).

CONCLUSION

For the foregoing reasons, Lilly's motions *in limine* should be denied.

Date: February 17, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a) on February 17, 2017. As such, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A).

Date: February 17, 2017

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